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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,681	06/13/2006	Thomas A. Brandt	PC26214A	4963
28523	7590	04/06/2009	EXAMINER	
PFIZER INC.			YOUNG, SHAWQUIA	
PATENT DEPARTMENT, MS8260-1611				
EASTERN POINT ROAD			ART UNIT	PAPER NUMBER
GROTON, CT 06340			1626	
			NOTIFICATION DATE	DELIVERY MODE
			04/06/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

-IPGSGro@pfizer.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/582,681	BRANDT, THOMAS A.
	<b>Examiner</b>	<b>Art Unit</b>
	SHAWQUIA YOUNG	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>10/12/06</u> .	6) <input type="checkbox"/> Other: ____ .

## **DETAILED ACTION**

Claims 1-7 are currently pending in the instant application.

### **I. *Priority***

The instant application is a 371 of PCT/IB04/03815, filed on November 22, 2004 which claims benefit of US Provisional Application 60/526,546, filed on December 2, 2003.

### **II. *Information Disclosure Statement***

The information disclosure statement (IDS) submitted on October 12, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### **III. *Rejections***

#### ***35 USC § 103 - OBVIOUSNESS REJECTION***

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

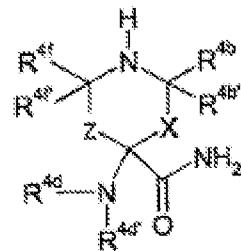
*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine

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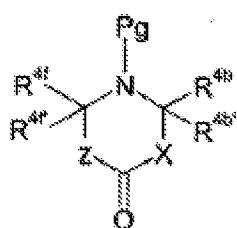
obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Carpino, et al.* (US 2004/0248881 A1) in view of *Katritzky, et al.* Applicants claim a

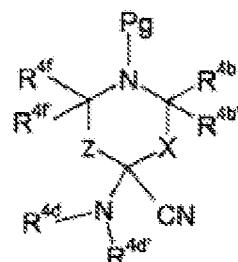


process for preparing a compound of the formula (1) wherein all variables are as defined in claim 1 comprising the steps of (1) reacting a compound of the formula  $R^{4d}\text{-NH-}R^{4d'}$  and a cyanide source with a compound of the formula



(1a)

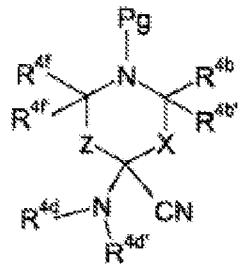
to form an intermediate of the formula



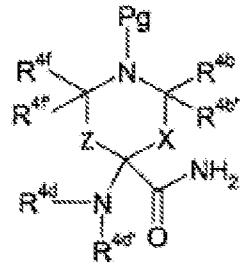
(1b)

where

$Pg$  is an amino-protecting group (2) hydrolyzing the nitrile group of a compound of the



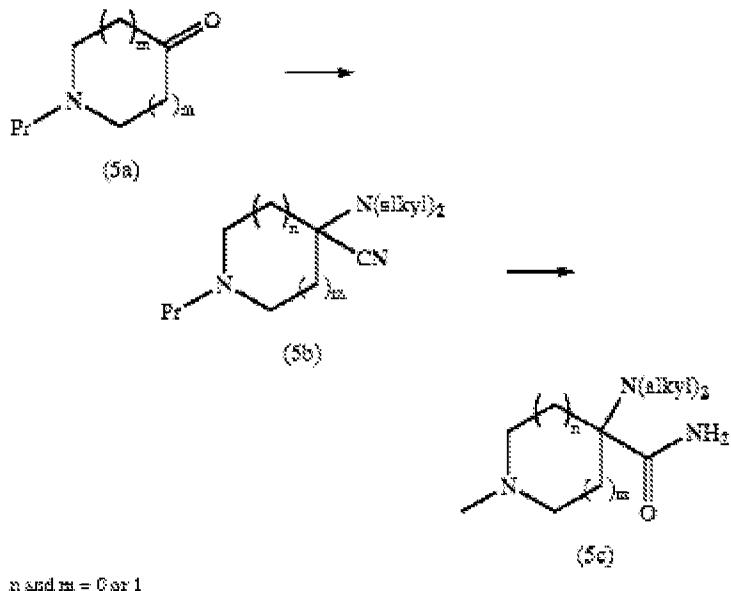
formula (Ib) with alkaline hydrogen peroxide in the presence of



dimethylsulfoxide to form a compound of the formula (Ic) (3) removing the amino-protecting group to form the compound of formula I and (4) optionally forming a pharmaceutically acceptable salt of said compound of Formula (I).

**The Scope and Content of the Prior Art (MPEP §2141.01)**

*Carpino, et al.* teaches the following process



$n$  and  $m = 0$  or  $1$

where the piperidinone

(5a) is reacted with the desired alkylamine and potassium cyanide in an aqueous HCl/ethanol solvent mixture at about 0°C to about 30°C to produce cyano intermediate (5b). Then the cyano group is converted to the corresponding amide with acid and water. The protecting group is then removed using conventional methods (See page 19, paragraph 0207).

*Katritzky, et al.* teaches a process for converting nitriles to amides with basic hydrogen peroxide in dimethyl sulfoxide.

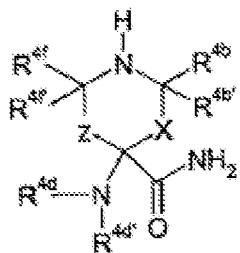
#### **The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art of *Carpino, et al.* and the instant invention is that there is homologous subject matter. The difference between the prior art and the instant claims is that the instant process uses alkaline hydrogen peroxide in the presence of dimethylsulfoxide in step (2) for hydrolyzing the nitrile group to an amide

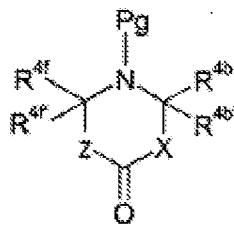
group whereas the prior art's process uses acid and water. The Katritzky, et al. teaches a process for an efficient conversion of nitriles to amides with basic hydrogen peroxide in dimethyl sulfoxide.

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

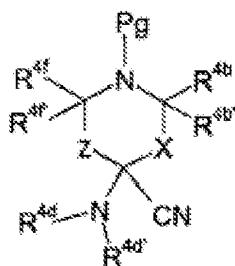
Applicants are claiming a process for preparing a compound of the



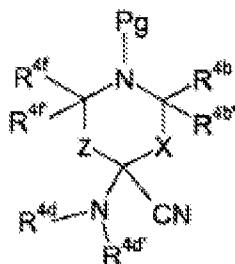
formula (a) wherein all variables are as defined in claim 1 comprising the steps of (1) reacting a compound of the formula  $R^{4d}\text{-NH-}R^{4d}$  and a cyanide source



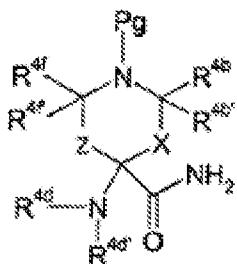
with a compound of the formula (a) to form an intermediate of the



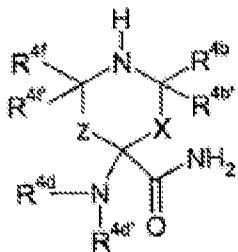
formula (b) where Pg is an amino-protecting group (2) hydrolyzing the



nitrile group of a compound of the formula (Ib) with alkaline hydrogen peroxide in the presence of dimethylsulfoxide to form a compound of the formula



(Ic) (3) removing the amino-protecting group to form the compound of formula I and (4) optionally forming a pharmaceutically acceptable salt of said compound of Formula (I). The Carpino, et al. reference teaches the reaction but the only difference is the use of an acid in water to hydrolyze the nitrile group in step (2) instead of alkaline hydrogen peroxide in dimethylsulfoxide. The Katritzky, et al reference teaches the use of basic hydrogen peroxide in dimethylsulfoxide for the conversion of a nitrile to an amide. It would be obvious for one of ordinary skill in the art to develop a process for preparing a compound of the formula



(i)

based on a process that is well-known in the art (US

2004/0248881 A1) and modifying the reaction conditions for step that involves the conversion of the nitrile group to an amide based on the teachings of the Katritzky, et al reference which teaches an "efficient conversion of nitriles to amides with basic hydrogen peroxide in dimethyl sulfoxide" which is the same reaction conditions that Applicants used in the claimed process.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the primary reference of Carpino, et al. which teaches a process for preparing a similar compound using similar process steps as seen in Applicants' claims with the secondary reference of Katritzky, et al. which teaches an efficient process to convert nitriles to amides with basic hydrogen peroxide in dimethyl sulfoxide with a reasonable expectation of success. A strong *prima facie* obviousness has been established.

#### **IV. Objections**

##### ***Specification***

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class.

For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

**V. Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626

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